oll Pharmaceutical Company

USA000670				
JF/Dist report #				
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<u> </u>			FOA Us	Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

			*	
ge 1 of 2			i	FDA Use Only
	otion/o			
C. Suspect medication 1. Name (give labeled strength & r	mir/labeler i	known)		··· t
**********	minacerer.		1	
VICODIN				
2 TYLENOL				
. Dose, frequency & route used		3. Therapy of	lates (if unkno	wn, give duration)
1 TAB UNK PO		#1 24-E	EB-94 t	O UNK
1 TAB UNK PO		#2 24-7	PR-94 t	nt abated after use stopped
1. Diagnosis for use (indication)				ose reduced
l <u>1 * </u>			- 1-1	yes no⊠ doesn't
#2 *			₁₂	ves no doesn't
6. Lot # (if known)	7. Exp. 0	tate (if known)	"2 \ .	yes no \(\bigsize \) doesn't apply
et UNK	#1 Unk	nown	8. Eve	nt reappeared after troduction
2 UNK	#2 Unk	nown		yes no doesn't
9. NDC # - for product problems				apply _
	#2 NI		#2	yes 🗌 no 🔯 doesn't
#1 NI			de ten stempel	apply apply
10. Concomitant medical produc	cts and there	DF	CEI	/ED
		1 -		and the second of the second
Name: none Dates:		1 FE	B 0 5	199¢
		1		
	****	.i.		
G. All manufactu 1. Contact office - name/address	e /& mining	sita for devices	1	2. Phone number
Knoll Pharmacautic				(973) 426-2600
3000 Continental D	rive -	North		3. Report source
Mount Olive, New J	erbey 0	7428-123	L	(check all that apply)
	الريبة الب	()		foreign
				study
FEI	B 0 8	1999		
				l consumer
SOMEONE THE		TO SVS	u	health professional
4. Date received by manufactur	rer jo.)NDA # 88	-058	user facility
02/05/98	1 1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Company
		IND#		representative
6. If IND, protocol #	İ	PLA #		distributor
:		pre-1938	yes	other:
7. Type of report		отс	П.,	
(check all that apply)		product	yes	UNITED STATES
☐ 5-day 🛭 15-day	6.	Adverse ever	nt term(s)	
10-day periodic	۸ ا	CIDOSIS	NOS, HEP	ATIC NECROSIS,
Initial K follow-up &	.1 0	HOLESTAS	IS, GAST	RIC HAEMORRHAGE
Limital V S long of the	s			OS, BRONCHITIS
9. Mfr. report number	. N	OS, PULM	ONARY CO	NGESTION,
USA000670	۲	RINARY B	LAUDER H	AEMORRHAGE, *
E Initial report	er			
E. Initial report				
i				
Dr.				•
	79	SA *		
2. Health professional?	3. Occu	pation	4. 1	nitial reporter also sent report to FDA
🛛 yes 🗍 no	1	CIAN		∐yes □ no ⊠u

Patient in	iformation			
Patient identifier			3. Sex	4. Weight
, =	Age at tigne of event:	43 yrs	ļ <u>_</u>	UNIK Ibs
	or —		[] female	or
in confidence	Onte of birth:		⊠ male	UNK kgs
		oduct prob	em	
Adverse ever		Product pro	blem (e.g., defect	s/malfunctions)
Outcomes attribute				
(check all that apply))	무 ~~	•	
death 05/	06/94		penital anomaly sired intervention to	prevent
life-threateni	•	beu.	nanent impairment	damage
hospitalizati	on - initial or prok	onged 🔲 othe	or.	
23 1000		4 Date		
3. Date of O	4/26/94	this	eport 01/29	/99
(meday/yr)		(me/day		
5. Describe event or p				
Acidos	is; centr	ilobular n	ecrosis;	
choles	tasis; ga	stric and	bladder her	morrhage;
spleni	tis; brone	chitis and	pulmonary	
conges	tion lead	ing to dea	th	
LITERA	TURE STUD	Y		
Notifi	cation vi	a litigati	on of case	
diimma T	ies provi	ded by phy	sician/aut	hor of
litera	ture repo	rt (NEJM 1	997, 337,	1112-7).
Inform	ation pro	wided base	d on extra	cted data
<u> </u>				
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report revealed; no apparent cirrhosis, Submission of a report does not constitute a admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event liem completed on continuation pages.

oll Pharmaceutical Company

	4.2			
	A.1. Patient Identifier	G.9. Mfr. report number	4 .	
MED WATCH		USA000670		Page 2 of 2
INTER AATTECT				

[continuation:] 26-Apr-1994, patient was admitted to ICU with lactic acidosis and oliguria. Patient later developed portal systemic encephalopathy, acute respiratory distress syndrome and coagulopathy. Patient was treated with acetylcysteine and put on dialysis. According to extracted data patient expired on 06-May-1994. Diagnosis upon death includes centrilobular congestion and atrophy consistent with centrilobular necrosis, severe cholestasis, and mucosal hemorrhage of stomach and bladder, splenitis, bronchitis with tracheitis and pulmonary congestion. There was no cirrhosis noted. No further information is expected.

Follow-up #1 (25-Jan-1999): The hospital admission note revealed the patient took 2 tablets of Vicodin and 2 tablets of Tylenol 2 days prior to admission (24-Apr-1994). The patient presented with decreased systolic blood pressure and acute hepatic failure. The treatment plan inclu ed antibiotics. The final autopsy report listed the principal diagnosis as massive centrilobular hepatic necrosis, diffuse alveolar damage of lungs, exudative phase, and bronchopneumonia

B.5. Relevant tests/laboratory data, including dates

[continuation:] MBsAg=neg, a-HBc=neg, a-HVC=neg, ANA=neg

B.7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use. hepatic/renal dysfunction, etc.) [continuation:] the presence of ascites, muscle wasting and testicular atrophy are consistent with the effects of chronic liver disease

C.4. Diagnosis for use (indication) (Suspect #1)

abdominal pain, flu-like symptoms

C.4. Diegnosis for use (indication) (Suspect #2)

abdominal pain, flu-like symptoms

G.S. Adverse event term(s)

[continuation:] OLIGURIA, ENCEPHALOPATHY NOS, ADULT RESPIRATORY DISTRESS SYNDROME, COAGULATION DISORDER NOS, HYPOTENSION, HEPATIC FAILURE, LUNG DISORDER NOS, PNEUMONIA NOS

E.1. Name, address & phone #

[continuation:] Phone:

FEB (18 1999)

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